K111091

JUN 24 2011

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4196 (801) 253-6932 Michaela Rivkowich April 14, 2011 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	To be assigned Merit Medical 20 ml Syringe Syringe, Piston
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit Medical 1-mL Syringe Syringe, Piston K024052 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 880.5860 General Hospital	
Intended Use	The Merit Medical 20 ml Syringe is used to inject fluids into, or withdraw fluids from, the body.	
Device Description	The Merit Medical 20 ml Syringe is a device consisting of a calibrated hollow barrel into which is inserted a closely fitting movable plunger and seal. The barrel contains a male Luer Lock connector which is compatible for attaching devices with standard female Luer hubs.	
Technological Characteristics	The technological characteristics of the subject Merit Medallion Syringe are substantially equivalent to those of the predicate device, the Merit Medical 1-mL Syringe, 510(k) K024052.	

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit Medical 20 ml Syringe was conducted based on the risk analysis and based on the requirements of the following FDA guidance document and international standards:

- *Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes,* April 1993
- ISO 7886-1:1993, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use*
- ISO 594-1:1986, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*
- ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- ANSI/AAMI/ISO 11135-1: 2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-1: 2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile
- EN ISO 10993-7:2008, *Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals*

The following is a list of all significant testing that was successfully completed:

Cleanliness
Limits for acidity and alkalinity
Limits for extractable metals
Inspection for lubricant contaminants
Tolerance on graduation capacity
Graduated scale
Numbering of scale
Overall length of scale to nominal capacity
Position of scale
Barrel – finger grips
Piston/plunger assembly – design
Piston/plunger assembly – fit of piston in barrel
Piston/plunger assembly – fiducial line
Gauging
Separation force
Unscrewing torque
Ease of assembly
Resistance to overriding
Resistance to cracking

Safety & Performance Tests cont.	Position of nozzle on end of barrel Nozzle lumen Dead space Freedom from air leakage Freedom from liquid leakage Freedom from liquid leakage with side force Adhesion of ink Biocompatibility tests Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Hemocompatibility Packaging performance after exposure to accelerated aging and simulated shipping and handling conditions: Visual inspection Dye penetration testing Underwater leak test (bubble emission testing) Seal strength-seal peel tensile strength Burst pressure testing
Safety & Performance Tests cont.	The results of the testing demonstrated that the subject Merit Medical 20 ml Syringe met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, and safety and performance testing, the subject Merit Medical 20 ml Syringe meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Medical 1-mL Syringe, manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michaela Rivkowich
Principal Regulatory Affairs Specialist
Merit Medical Systems, Incorporated
1600 West Merit Parkway
South Jordan, Utah 84095

JUN 24 2011

Re: K111091
Trade/Device Name: Merit Medical 20 ml Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 24, 2011
Received: May 26, 2011

Dear Ms. Rivkowich

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K111091

Device Name: Merit Medical 20 ml Syringe

Indications for Use:
The Merit Medical 20 ml Syringe is used to inject fluids into, or withdraw fluids from, the body.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Rick Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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